Siam Sempermed Corp., Ltd.

DEC - 4 2000

K002391

510(k) SUMMARY

07072000

1.0 APPLICANT:

Dr. POONSUK CHERDKIATGUMCHAI
SIAM SEMPERMED Corp., Ltd.
110 MOO 8 KANJANAVANIT ROAD
PATHONG HATYAI SONGKHLA
THAILAND 90230
TEL: 66 074 291 648 OR 291 649
FAX: 66 074 291 650

2.0 CONTACT PERSON

Dr. POONSUK CHERDKIATGUMCHAI
SIAM SEMPERMED CORPORATION.,Ltd
110 MOO 8 KANJANAVANIT ROAD
PATHONG HATYAI SONGKHLA
THAILAND 90230
TEL: 66 074 291 648 OR 291 649
FAX: 66 074 291 650

Mr. William Harris
SEMPERMED USA Corp.,Ltd.
30798 US HWY 19N
PALM HARBOR
USA FL 34684
TEL: 727 787 7250
FAX: 727 787 7558

3.0 Device Class: I
Product code: 80LZA

4.0 Specification: Class I Nitrile patient examination glove-80LZA (Powdered) meets all of the requirements of ASTM standard D 3578 (with the exception of elongation)

5.0 Device Description: Nitrile Patient Examination glove (Powdered)

6.0 Intended use: A glove is worn on the hand of health care and similar personnel to prevent contamination between healthcare personnel and the patient's body, fluids, waste, or environment

7.0 Outer surface: Free from talc (Magnesium silicate)

8.0 Primary Dermal Irritation in Rabbits Guinea Pig Sensitization (Buehler): Consumer Product Testing Co.
Experiment reference number : T00-0088-3

Conclusion : According to Federal Hazardous Substances Act Regulations, (16 CFR 1500.41), and under the conditions of this test, this test article is not a primary dermal irritant.

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9.0 QUALITY CHARACTERISTICS

Dimensions	Meet ASTM D 3578
Physical Properties	Meet ASTM D 3578
Freedom from pinholes	Meet ASTM D 3578 Meet ASTM D 5151
Powder	1.8+/- 1.0% by weight

10. Conclusion: Siam Sempermed Nitrile Patient Examination Glove (Powdered)
meet the ASTM standard or equivalent standard
meet pinhole FDA requirements
meet labeling claims (see 5.0 and 6.0 above)

P. Cherdkiatgumchai

Dr. POONSUK CHERDKIATGUMCHAI
Chief Quality Officer

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 2000

Siam Sempermed Corporation Limited
C/O Mr. William Harris
Sepermed USA, Incorporated
30798 US Highway 19 North
Palm Harbor, Florida 34684

Re: K002391
Trade Name: Nitrile Patient Examination Glove, Powdered Non-Sterile
Regulatory Class: I
Product Code: LZA
Dated: October 18, 2000
Received: October 23, 2000

Dear Mr. Harris:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

0 Indications for Use Statement: Include the following or equivalent Indications for Use page. The information, data and labeling claims in the entire the 510(k) submission must support and agree with the Indications for Use statement.

INDICATIONS FOR USE

Applicant: Siam Sempermed Corporation., Ltd

510(k) Number (if known): K002391*

Device Name: Nitrile Patient Examination glove (powdered)

Indications For Use:

" A patient examination glove is a disposable device intended for medical purposes worn on the examiner's hand or finger to prevent contamination between patient and examiner "

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter X

Per 21 CFR 801.109

(Optional Format 1-2-96)

* For a new submission, do NOT fill in the 510(k) number blank.

Signed for Clin

(Division Sign-Off)

Division of Dental, Infection Control, and General Hospital Devices

510(k) Number K002391

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